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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re EFFEXOR XR ANTITRUST LITIGATION This Document Relates To: Direct Purchaser Class Actions	Master Docket No. 3:11-cv-05479 (PGS/LHG)

DIRECT PURCHASER CLASS PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR ENTRY OF FINAL JUDGMENT UNDER FED. R. CIV. P. 54(b) OR, IN THE ALTERNATIVE, CERTIFICATION OF APPEAL PURSUANT TO 28 U.S.C. § 1292(b)

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Direct Purchaser Class Plaintiffs ("Plaintiffs")[1] respectfully move for entry of partial final judgment pursuant to Fed. R. Civ. P. 54(b) or, in the alternative, certification for interlocutory appeal pursuant 28 U.S.C. § 1292(b).

I. INTRODUCTION

On October 7, 2014, the Court dismissed Count II of Plaintiffs' Second Consolidated Amended Class Action Complaint (the "Complaint") [ECF #287] with prejudice.[2] The Court's Opinion (the "Opinion" or "Op.") [ECF # 353] holds, as Plaintiffs have long argued, that *F.T.C. v. Actavis*[3] compels a finding that non-cash reverse payment settlement agreements ("RPSA") may violate the antitrust laws. But, the Court adopted a new, heightened pleading standard requiring antitrust plaintiffs challenging non-cash payments to "provide appropriate *evidence* for the Court to determine the value of the payment,"[4] which must be "based on a reliable foundation used within the industry."[5] In dismissing with prejudice, the

[1] Plaintiffs are Professional Drug Company, Inc., Rochester Drug Co-Operative, Inc., Stephen L. LaFrance Holdings, Inc., Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors, and Uniondale Chemists, Inc.

[2] ECF # 353 (Memorandum) and # 354 (Order).

[3] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

[4] Op. at 40.

[5] Op. at 38.

Court found "[t]he Complaint simply does not rely on any knowledge of business practitioners in the pharmaceutical industry."[6]

Plaintiffs respectfully believe that the Court erred in: (1) establishing a new pleading standard imposing a level of particularity and precision beyond that required by the Supreme Court and the Federal Rules of Civil Procedure; (2) dismissing Plaintiffs' RPSA claims "with prejudice," without an opportunity to re-plead in light of this new pleading standard (and without considering Plaintiffs' submission setting forth a plausible methodology for calculating the value of the "no AG" payment); and (3) holding that the reverse payment was not "unexplained" within the meaning of *Actavis*, when in fact the large reverse payment alleged in the Complaint was unexplained by any legitimate pro-competitive effects (and thus could be explained only by the anticompetitive effects that it bought (delayed generic entry and the higher prices resulting from that delay.)

Plaintiffs have contemporaneously filed a motion for reconsideration of the Court's "with prejudice" dismissal along with a motion to amend the complaint.[7] If those motions are denied, Plaintiffs make this motion pursuant to Fed. R. Civ. P. 54(b) for entry of partial final judgment or, in the alternative, 28 U.S.C. § 1292(b)

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[6] Op. at 39.

[7] *See* Direct Purchaser Class Plaintiffs' Motion For Reconsideration To Allow Repleading, dated October 21, 2014.

for certification of the three issues described above (and specified below) for interlocutory appeal.

Entry of partial final judgment under Rule 54(b) is appropriate because the Order and Opinion provide a final adjudication of Count II (the only claim against Defendant Teva), and because there is no just reason for delay. Certification for interlocutory appeal under Section 1292(b) is appropriate because the Court's Opinion involves controlling issues of law as to which there are substantial grounds for a difference of opinion, and certification would materially advance the outcome of the litigation. In the event the Court grants either form of relief, Plaintiffs intend to move the Third Circuit to expedite the appeal, allowing for an appellate resolution of Count II before a trial on Count I, in order to conserve the courts' and the parties' resources and litigate these claims efficiently.

II. BACKGROUND

Plaintiffs, direct purchasers of the drug Effexor XR, are seeking recovery of overcharges caused by the Defendants' antitrust violations.[8] In addition to a *Walker Process* claim against Wyeth (Count I) that survived a motion to dismiss, Plaintiffs allege, in Count II, that Wyeth and Teva violated the Sherman Act by entering into an RPSA which included a payment from Wyeth to Teva in exchange

[8] Defendants are Wyeth LLC, Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall Pharmaceuticals LLC, and Wyeth Pharmaceuticals Company (collectively, "Wyeth") and Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd.'s (collectively, "Teva").

for Teva's promise to delay generic entry into the Effexor XR market.[9] That payment took the form of, *inter alia*, a promise from Wyeth to Teva "that Wyeth would not market an authorized generic version of Effexor XR during Teva's 180-day exclusivity period."[10]

In exchange for Teva's delayed generic launch date, Wyeth agreed not to launch an authorized generic, handing Teva the entire generic Effexor XR market for a period of at least six months.[11] Without competition from Wyeth's authorized generic, Teva was able to roughly double its sales *and* make each sale at a higher, supra-competitive price.[12] The value to Teva of this payment was approximately $500 million.[13]

This Court held that existing Rule 12(b)(6) standards must be applied "against the factors of *Actavis* in analyzing the Plaintiff's complaint."[14] The Court

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[9] Op. at 1-2 ("Plaintiffs allege that Wyeth . . . entered into an illegal horizontal market-allocation and price-fixing reverse settlement agreement with Defendant Teva through which Wyeth paid Teva value worth over $500 million in exchange for Teva's agreement not to market its own generic version of Effexor XR until an agreed-upon entry date.")

[10] Op. at 19. In addition, Wyeth provided other valuable consideration to Teva by granting Teva an exclusive license to market generic Effexor IR with a no-AG promise. Complaint, ¶¶ 273-275.

[11] Complaint, ¶ 12.

[12] *Id.*, ¶¶ 12, 275-287.

[13] *Id.*, ¶¶ 12, 275-287; *see also* May 19, 2014 letter brief [ECF # 332] (setting forth methodology for calculating the amount of the payment from Wyeth to Teva).

[14] Op. at 27.

identified four "*Actavis* factors": (1) there must be a "payment"; (2) it must be a "reverse" payment; (3) it must be "large"; and (4) it must be "unexplained."[15]

Applying "this new *Actavis* framework,"[16] the Court began by noting that "*Twombly* and *Iqbal* establish a flexible pleading benchmark."[17] The Court held that a plaintiff seeking to satisfy this standard as to a complaint alleging a non-monetary payment must, through the use of facts, make "a showing of a reliable foundation used within the industry to convert the non-monetary payment to a monetary value.[18]

While Plaintiffs alleged the value of the payment to Teva was approximately $500 million, according to the Court, "Plaintiffs' calculation of the monetary value of the no-authorized generic agreement is vague and amorphous" and could not "raise a right to relief above the speculative level" because Plaintiffs failed to "present specific facts showing how the alleged non-monetary payment was calculated."[19] It did not consider Plaintiffs submission detailing a "methodology

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[15] Op. at 32. (citing *Actavis*, 133 S. Ct. at 2236-37)

[16] Op. at 33.

[17] Op. at 36.

[18] Op. at 36.

[19] Op. at 38. The Court denied Plaintiffs request for leave to amend in the event it granted defendants' motion. Plaintiffs' Opp. to Mot. to Dismiss [ECF No. 316] (Jan. 24, 2013) at 20

used to calculate the no authorized generic agreement having a value of over $500 million."[20]

The Opinion also holds that the payment was not "unexplained" within the meaning of *Actavis*, because the submission of the agreement to the FTC, and the FTC's "lackluster response" thereto, constituted a "sufficient justification" for the agreement.[21] The Court made this finding despite the fact that the record does not demonstrate that either the patent case judge or the FTC made any explicit investigation into, nor did either comment on, the settlement's effect on competition. To the contrary, while the settlement agreement was produced to the FTC, the FTC informed Wyeth (which, in turn informed the patent court) that it would not object at that time because Wyeth and Teva had indicated they would not raise the issue of "competitive implications" before the patent court. The FTC expressly cautioned that its decision did not mean that the settlement was lawful. The consent decree was entered after the FTC's reservation of rights.

[20] Op. at 38 n.20. Because the Court did not believe that the value of the payment was sufficiently alleged, it also found that the Plaintiffs did not adequately allege that the payment was "reverse" and "large." Op. at 40-42.

[21] Op. at 42-43.

III. THIS COURT SHOULD ENTER PARTIAL, FINAL JUDGMENT ON COUNT II

A. Legal Standards Governing Motions Entry of Final Judgment Pursuant to Rule 54(b)

Rule 54(b) permits a district court, in cases involving multiple claims or multiple parties, to sever one or more individual claims that have been fully resolved, and issue a final judgment from which the losing party may immediately appeal. Whether to grant Rule 54(b) certification is "left to the sound judicial discretion of the district court", which should exercise that discretion "in the interest of sound judicial administration."[22]

"A decision to certify a final decision under Rule 54(b) involves two separate findings: (1) there has been a final judgment on the merits, *i.e.*, an ultimate disposition on a cognizable claim for relief; and (2) there is 'no just reason for delay.'"[23] "The function of the district court under the Rule is to act as a 'dispatcher' ... to determine the 'appropriate time' when each final decision in a multiple claims action is ready for appeal."[24]

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[22] *Curtiss–Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 8 (1980).

[23] *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 202 (3d Cir. 2006) (quoting *Curtiss-Wright*, 446 U.S. at, 7-8).

[24] *Curtiss-Wright*, 446 U.S. at 8 (quoting *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 435 (1956)).

B. Entry of Final Judgment is Appropriate in this Case

The first part of the Rule 54(b) inquiry requires that the claim certified for immediate appeal "must be a 'judgment' in the sense that it is a decision upon a cognizable claim for relief, and it must be 'final' in the sense that it is 'an ultimate disposition of an individual claim entered in the course of a multiple claims action.'"[25] Here, there can be no doubt that the Court's dismissal of Count II (Plaintiffs' RPSA claim) is "final." Assuming the Court does not grant reconsideration or leave to amend, that decision terminates the litigation as to that claim. It also terminates the litigation as to Defendant Teva, which is not a party to Count I, the *Walker Process* claim upheld by the Court.

C. There is No Just Reason to Delay Resolution of Plaintiffs' Appeal

Entry of final judgment as to Count II is appropriate because there is no just reason for delay. In determining whether there is just reason for delaying Plaintiffs' ability to appeal the dismissal of Count II, the Court "must take into account judicial administrative interests as well as the equities involved."[26] "[T]he rule was designed in an attempt 'to strike a balance between the undesirability of

[25] *Curtiss–Wright*, 446 U.S. at 7 (quoting *Sears, Roebuck*, 351 U.S. at 436).

[26] *Curtiss-Wright*, 446 U.S. at 8.

piecemeal appeals and the need for making review available at a time that best serves the needs of the parties.'"[27]

To aid courts in determining whether there is no just reason for delay, the Third Circuit has identified five factors: "(1) the relationship between the adjudicated and unadjudicated claims; (2) the possibility that the need for review might or might not be mooted by future developments in the district court; (3) the possibility that the reviewing court might be obliged to consider the same issue a second time; (4) the presence or absence of a claim or counterclaim that could result in set-off against the judgment sought to be made final; and (5) miscellaneous factors such as delay, economic and solvency considerations, shortening the time of trial, frivolity of competing claims, expense, and the like."[28]

Factor 1: Relationship between adjudicated and unadjudicated claims

None of the issues Plaintiffs seek to bring before the Third Circuit with regard to Count II (the RPSA claim) overlap with the remaining claim in this case,

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[27] *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 202 (3d Cir. 2006) (quoting *Allis–Chalmers.*, 521 F.2d at 363).

[28] *Allis-Chalmers*, 521 F.2d at 364 (citations and footnotes omitted). The Supreme Court in *Curtiss-Wright*, 446 U.S. at 8-9, overruled *Allis-Chalmers* in part based on the Third Circuit's over-reliance on the existence of counterclaims (the fourth factor listed above) in deciding that case on the merits. However, the Court did not reject the factors themselves; rather, it emphasized the need for a balancing of all potential considerations of equity and judicial efficiency. *See id.* at 8 & fn.2. The Third Circuit has continued to apply the *Allis-Chalmers* factors. *See, e.g. Berckeley*, 455 F.3d at 203.

Count I (the *Walker Process* claim). This factor supports certification, as it tests whether there is any risk of an appellate court being twice presented with the same issues, or with issues that are intertwined with the claims that remain to be decided by the district court.[29] Nonetheless, "[i]t is generally recognized that complete legal or factual distinction is not necessary to 54(b) certification."[30]

The anticipated appeal would involve a limited set of issues unrelated to the remaining *Walker Process* claim: (1) the standards for pleading *Actavis*' requirement of a large, unexplained reverse payment; (2) the decision to dismiss Plaintiffs' RPSA claim with prejudice; and (3) whether the payments were "unexplained" within the meaning of *Actavis*. None of these issues will arise in Plaintiffs' *Walker Process* case. That claim is based on Section 2 of the Sherman Act (the anti-monopoly section), which does not require proof of an agreement, unlike the *Actavis* claim based on Section 1 (the anti-conspiracy section) of the Act. The *Walker Process* claim focuses on Wyeth's conduct before the PTO and its patent litigation against its would-be generic competitors, not on the value of the payments it made to Teva to stay off the market. Any other elements that

[29] *See Carter*, 181 F.3d at 346 (holding district court must determine separability of claims "such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals.").

[30] *Carter*, 181 F.3d at 346 n.20.

overlap between Plaintiffs' two antitrust claims are not ripe at this point, and therefore will not be considered by the Third Circuit in the instant appeal.[31]

Further, the fact that Count II involves an additional party, Teva, that is not a party to Count I, is an additional reason favoring 54(b) certification. The Third Circuit has held 54(b) certification was proper in a similar case where the district court's directed verdict in phase one of a two-phase trial led to the dismissal of one of the two defendants.[32]

Factor 2: Possibility of Further Developments Mooting Need for Review

This factor is no obstacle to Rule 54(b) certification. The only possible event that could moot the need for appellate review of the Order and Opinion would be a decision by this Court reconsidering its dismissal of Count II. Therefore, Plaintiffs seek Rule 54(b) certification in the alternative to their motion to reconsider and/or amend. The key questions leading to dismissal of Count II, as

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[31] *Cf. Medrad, Inc. v. Tyco Healthcare Grp., LP*, CIV.A. 01-1997, 2005 WL 3466038, at *2 (W.D. Pa. Dec. 19, 2005) (finding patent claim and antitrust counterclaim were separable because potentially overlapping factual issues fell outside the scope of the appeal: "Although defendants have based their antitrust counterclaim, in part, on allegations of inequitable conduct during the prosecution of the '602 reissue patent, and its predecessors, our October 12, 2005 decision did not consider such facts.").

[32] *Genty v. Resolution Trust Corp.*, 937 F.2d 899 (3d Cir. 1991) ("Although the plaintiffs in both phases of the lawsuit are the same, the defendants are entirely different parties, except for the Township which is a defendant in both phases.").

described under Factor 1 above, will most likely not be reconsidered or mooted in the course of litigating Count I.

Factor 3: Whether reviewing court may consider the same issue twice

There is no danger of the Third Circuit being twice faced with the question of whether Plaintiffs sufficiently pled a large, unexplained reverse payment, and whether a dismissal "with prejudice" was appropriate, which are the core issues ripe for appeal. And, none of the additional issues or elements that may overlap between Plaintiffs' two antitrust claims will be at play in Plaintiffs' appeal here.[33]

Factor 4: Presence or Absence of Counterclaims

This factor supports Rule 54(b) certification as there is no basis for either Teva or Wyeth to assert any counterclaims or right of setoff against the Direct Purchaser Plaintiffs or against each other.

Factor 5: Miscellaneous factors such as delay or expense

The miscellaneous criteria strongly favor granting the requested relief. Rule 54(b) certification could avoid the tremendous waste of the courts' and the parties' time and resources that would occur if the Third Circuit were to reinstate Count II

[33] *Commissariat A L'Energie Atomique v. Chi Mei Optoelectronics Corp.*, 293 F. Supp. 2d 430, 435 (D. Del. 2003) (granting 54(b) certification where "there is no significant risk of duplicative appeals, since the claims against CMO were dismissed for lack of personal jurisdiction, an issue which is not present, at least at this juncture, in any of the remaining claims."), *vacated on other grounds*, 395 F.3d 1315 (Fed. Cir. 2005).

after the parties had litigated Count I to its termination. Discovery would need to be reopened as to Wyeth and commence as to Teva which, no longer a party, would not be involved in most of the ongoing discovery related to Count I; Plaintiffs would likely have to re-depose many of the same witnesses whose depositions they took under Count I; class certification might need to be re-briefed; and the parties' experts would be required to draft additional and costly class and merits expert reports.[34]

Worse, there would be a substantial risk that, absent immediate certification of the above-described issues relating to Count II, two separate trials, with different juries, may result in potentially inconsistent damage awards for the proposed Class's overcharges. The wrongful conduct alleged in Count I (*Walker Process*) and Count II (anticompetitive reverse payment agreement) delayed generic entry and created overcharge damages. To measure the extent of those damages, it is necessary to determine the length of the delay caused by Defendants' wrongful conduct. If Plaintiffs win under Count I, the period of delay would likely run from the expiration of the Husbands patent (June 13, 2008). If Plaintiffs win under Count II, the period of delay would likely run from the date on

[34] *Cf. Commissariat A L'Energie*, 293 F. Supp. 2d at 435 (finding 54(b) certification promoted judicial economy because a reversal of court's dismissal order on appeal would make reinstated claim "'more likely to be resolved in the same time frame as the claims against the other defendants in this action'", quoting *Carter v. City of Philadelphia*, 181 F.3d 339, 347 (3d Cir. 1999)).

which the jury determines Teva would have come to market if the parties had entered a lawful agreement (not containing a reverse payment), a date which could be later than June 13, 2008. Wyeth is solely responsible for the damages under Count I; Wyeth and Teva are jointly responsible for the damages under Count II, with no right of contribution as against one another. If two trials are held, and two juries find for Plaintiffs but assign different entry dates, there is a risk of double damages being assessed.[35]

On the other side of the scale, allowing an immediate appeal would occasion little delay or inconvenience to the Court or the parties: discovery has not yet begun in earnest, and there are no other crucial events arising in the immediate future that would be disrupted by a ruling from the Third Circuit on Count II. Discovery on the *Walker Process* claim could proceed at the same time as the appeal of Count II. It is unlikely that the *Walker Process* claim would be ready for trial before such an appeal is decided. And when the appeal is decided, the parties

[35] *See Carter v. City of Philadelphia*, 181 F.3d 339, 347 (3d Cir. 1999) (finding 54(b) certification appropriate where "denial of an immediate appeal may pose a substantial risk that the District Court and the parties will be forced to undergo duplicative trials."); *Chamberlain v. Harnischfeger Corp.*, 516 F. Supp. 428, 430 (E.D. Pa. 1981), *aff'd*, 673 F.2d 1298 (3d Cir. 1981) (finding risk of duplicate trials and inconsistent judgments warranted 54(b) certification: "Plaintiff may now still litigate against Phillips in another judicial district but he will then be pursuing claims in two courts, with the possibility of inconsistent determinations in the trial courts and on appeal.").

will be in position to conduct a single trial.[36] Weighing all considerations of judicial efficiency and fairness to the parties, this Court should certify its order for immediate appeal under Rule 54(b).

IV. ALTERNATIVELY, THIS COURT SHOULD CERTIFY ISSUES FOR APPEAL UNDER 28 U.S.C. § 1292(b).

Plaintiffs seek certification of three issues:

1. Whether plaintiffs alleging a non-cash reverse payment under *Actavis* must include in their complaint, prior to discovery, *evidence* allowing the court to determine the value of the payment "based on a reliable foundation used within the industry," including "knowledge of business practitioners in the pharmaceutical industry."

2. Whether the Court erred in granting a motion to dismiss "with prejudice" where (a) the Court evaluated the complaint under a new pleading standard, (b) Plaintiffs had asked for leave to amend in the event dismissal was granted, (c) the Court did not consider a proposed methodology that would have met the Court's new pleading standard, and (d) Plaintiff was not given an opportunity to re-plead.

3. Whether the Court erred in holding Defendants' submission of their agreement to the FTC, and the FTC's subsequent reservation of its rights, constituted a "sufficient justification" such that the payment was not "unexplained" within the meaning of *Actavis* when (a) the Defendants were required by statute to submit the agreement to the FTC; (b) *Actavis* focused on the competitive effects of reverse payment agreements rather than whether/when the FTC responded to such submissions, and (c)

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[36] If the *Walker Process* claim is trial-ready before the Third Circuit rules, the district court litigation could at that time be stayed. If the Third Circuit reverses on Count II, targeted discovery on the RPSA claim could occur and the claims be brought to a single trial. Any slight delay in a trial of the *Walker Process* claim pales in comparison to the risk of duplicative trials that may yield inconsistent verdicts. *Cf. Chamberlain*, 516 F.Supp. at 430 ("[P]laintiff prefers this delay to the prospect of two trials[.]").

neither the FTC nor the patent judge conducted a comprehensive review of the competitive effects of the agreement.

A. Legal Standards for Certification of a Question to the Court of Appeals

To certify a question for the Court of Appeals under Section 1292(b), this Court must find that (1) the certified order involves a controlling question of law; (2) there is substantial ground for difference of opinion with respect to that question; and (3) immediate appeal may materially advance the ultimate termination of the litigation.[37]

The question of whether to certify an appeal under Section 1292(b) lies within the discretion of the district court.[38] Interlocutory appeal should be utilized where "an immediate appeal has the potential to greatly conserve the resources of the judiciary and the parties."[39]

B. Certification Under § 1292(b) Should Be Granted

This Court has entered a lengthy opinion concerning an area of the law that

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[37] 28 U.S.C. § 1292(b); *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 754 (3d Cir. 1974); *Kaplan v. Saint Peter's Healthcare System*, No. 13-cv-2941, 2014 WL 4678059 (D.N.J. Sept. 19, 2014); *Huber v. Howmedica Osteonics Corp.*, No. 07-cv-2400, 2009 WL 2998160, *1 (D.N.J. Mar. 10, 2009); *New Jersey Protection & Advocacy, Inc. v. New Jersey Dept. of Ed.*, No 07-cv-2978, 2008 WL 469345, at *2 (D.N.J. Oct. 8, 2008).

[38] *Huber*, 2009 WL 2998160 at *1 (citation omitted).

[39] *Chase Manhattan Bank v. Iridium Africa Corp.*, 324 F. Supp.2d 540, 545-46 (D. Del. 2004).

is in flux following the Supreme Court's decision in *FTC v. Actavis*.[40] The pleading standard adopted by this Court for evaluating the allegations of a complaint alleging a non-cash reverse payment departs from the standard adopted by other district courts which have considered the same issue, warranting certification. And, the Court's decision to dismiss "with prejudice," without affording Plaintiffs the opportunity to meet this new standard, also warrants certification. Finally, certification is warranted with respect to the Court's unprecedented finding that Wyeth and Teva's statutorily-required submission of the challenged agreement to the FTC, and the FTC's no-action decision, warrants dismissal of Plaintiffs' RPSA claim under *Actavis*.

1. **The Court's opinion concerns "controlling issues of law."**

Questions of law can be "controlling" under numerous circumstances. The most obvious instance of a controlling question of law would be one that "'would result in a reversal of a judgment after final hearing'" if the Court's Order were reversed.[41]

But for a question of law to be controlling, there is no requirement that it would result in reversal of a judgment upon appeal; rather, a question is controlling

[40] __ U.S. __, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013).

[41] *See Elizabethtown Water Co. v. Hartford Cas. Ins. Co.*, 18 F. Supp.2d 464, 465 (D.N.J. 1998) (quoting *Katz*).

if it is "serious to the conduct of the litigation, either practically or legally."[42] The Third Circuit has noted that "on the practical level, saving of time of the district court and of expense to the litigants [is] a highly relevant factor."[43]

The issues on which Plaintiffs seek certification are "controlling." The pleading standard adopted by the Court – including its requirement that the Plaintiffs plead evidence to support their calculation of monetary value of the non-cash payment to Teva -- was clearly "serious to the conduct of the litigation."[44] Indeed, it was outcome determinative. Likewise, the Court's decision to dismiss with prejudice, and deny Plaintiffs an opportunity to meet this new standard, conclusively determined the fate of Count II. Similarly, the Court's decision that the Defendants' submission of the Wyeth-Teva agreement to the FTC and the FTC's subsequent non-action in response to the submission constituted a

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[42] *Id.*; *see also New Jersey Dept. of Treasury v. Fuld*, No. 09-cv-1629, 2009 WL 2905432, *2 (D.N.J. Sept. 8, 2009) (citing *Katz*); *New Jersey Protection.* 2008 WL 4692345, at *3 (discussing *Katz* standard for controlling questions of law).

[43] *Katz*, 496 F.2d at 755 (an order does not need to be determinative of plaintiff's claim on the merits or one that, if reversed, would terminate the litigation in order to be "controlling").

[44] *See, e.g., In re Text Messaging Antitrust Litigation*, 630 F.3d 622, 624 (7th Cir. 2010) ("[W]hen the question presented by an appeal is whether *Twombly* requires dismissal of a complaint, the concerns underlying that decision argue for empowering the district court and the court of appeals to authorize an interlocutory appeal."); *see also Florence v. Board of Chosen*, 621 F.3d 296, 301 (3d Cir. 2010) (when issue concerns application of the proper legal standard, it is a controlling question within the meaning of section 12929(b)).

"sufficient justification," and the payment therefore was not an "unexplained" payment within the meaning of *Actavis*, dictated the outcome of Count II.

2. There are substantial grounds for a difference of opinion concerning the Court's legal conclusions.

Substantial grounds for a difference of opinion exist whenever there is a genuine doubt or conflicting precedent as to the correct legal standard.[45] A lack of binding precedent can also support certification,[46] particularly where the issue presented is novel.[47] Here, certification is warranted under any of these tests.

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[45] *Kaplan*, 2014 WL 4678059 at *3.

[46] *In re Chocolate Confectionary Antitrust Litigation*, 607 F. Supp.2d 701, 706 (M.D. Pa. 2009) (citations omitted).

[47] *See Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd.*, 494 F. Supp. 1190, 1243 (E.D. Pa. 1980); *see also See, e.g.,Klinghoffer v. S.N.C. Achille Lauro Ed Altri-Gestione Motonave Achille Lauro In Amministrazione Straordinaria*, 921 F.2d 21, 25 (2d Cir. 1990) (accepting certification even though appeal did not present "controlling issue of law" because the issues presented were "difficult and of first impression"); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 600 (E.D. Pa. 2008) (finding substantial ground for difference of opinion on a preemption question where the question was "novel" and "the contours of the preemption doctrine with respect to pharmaceuticals . . . remain[ed] a pressing and hotly disputed topic"); *In re Currency Conversion Fee Antitrust Litigation*, 2005 WL 1871012, at *3 (S.D.N.Y. Aug. 9, 2005) ("An order may be certified for interlocutory appeal when the issues raised are novel and complex and where the practical effect of that order may be dispositive." (citations omitted)); *Padilla v. Rumsfeld*, 256 F. Supp.2d 218, 221 (S.D.N.Y. 2003) ("Courts have certified orders for interlocutory appeal when the issues they raise are difficult and novel, in addition to being potentially dispositive."); *Klapper v. Commonwealth Realty Trust*, 662 F. Supp. 235, 236 (D. Del. 1987) (substantial ground for difference of opinion where the issues "presents a 'case of first impression.'") (citation omitted).

a. There are substantial grounds for a difference of opinion concerning the Court's adoption of a new pleading standard.

What constitutes an actionable reverse payment in a post-*Actavis* world is currently the subject of significant judicial examination.

Two courts finding non-cash payments actionable under *Actavis*, did not require plaintiffs to attach a dollar value to such payments at the pleading stage. In *Niaspan*, the Eastern District of Pennsylvania concluded that allegations of valuable, non-cash payments in the form of no-AG agreements or other side deals were sufficient to state a plausible claim for relief under *Actavis* and the governing pleading standards.[48] The District of Massachusetts in *Nexium* also did not require plaintiffs to assign a dollar value to the challenged agreements, although it did cite the plaintiffs' allegations that attached an approximate dollar value to the agreements.[49] By contrast, in *Loestrin*, the District of Rhode Island was unwilling to apply *Actavis* to non-cash reverse payments, commenting (incorrectly, in Plaintiffs' view) that a non-cash payment is "almost impossible" to measure under

[48] *In re Niaspan Antitrust Litigation*, __ F. Supp.2d __, 2014 WL 4403848, at *11-12 (E.D. Pa. Sept. 5, 2014) (upholding RPSA claim alleging that a no-AG clause "can be worth several hundreds of millions of dollars").

[49] *In re Nexium (Esomeprazole) Antitrust Litigation*, 968 F.Supp.2d 367, 391-92 (D. Mass. 2013) (discussing plaintiffs allegations concerning reverse payments, including allegation that the no-AG clause was worth "over $1,000,000,000").

the *Actavis* test.[50] This Court has reached a different conclusion, imposing a heightened pleading standard requiring plaintiffs to plead *evidence*, with a reliable foundation used within the pharmaceutical industry, in order to explain the conversion of any non-cash payments to a cash value.[51]

There is genuine doubt as to the appropriate standard for assessing a complaint alleging a non-cash reverse payment. This Court's requirement that Plaintiffs utilize an industry-based foundation to convert a non-cash payment into a reliable cash value – but without the benefit of discovery regarding, *inter alia*, Wyeth and Teva's internal valuations of the deal – breaks new ground, and presents an issue ripe for certification.[52]

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[50] *In re Loestrin 24 FE Antitrust Litigation*, __ F. Supp.2d __, 2014 WL 4368924, at *9-10 (D.R.I. Sept. 4, 2014).

[51] Op. at 32-36 (requiring complaint to allege facts supporting a reliable industry foundation to prove how the cash value of the non-cash payment was calculated); *In re Lipitor Antitrust Litigation*, __ F. Supp.3d __, 2014 WL 4543502, at *20-21 (D.N.J. Sept. 12, 2014) (requiring plaintiff to allege facts and expert analysis, as if "standing in the shoes" of the defendant at the time the non-cash payment was made)

[52] *See, e.g., In re Chocolate Confectionary*, 607 F. Supp.2d at 707 (uncertainty concerning application of *Twombly* pleading standard warranted certification); *see also New Jersey Dept. of Treasury v. Fuld*, No. 09-cv-1629, 2009 WL 2905432, *2 (D.N.J. Sept. 8, 2009) ("[S]ubstantial grounds for difference of opinion may exist when the court is faced with issues of statutory interpretation that are somewhat novel and complex") (citation omitted); *Holliday v. Xerox Corp.*, 555 F. Supp. 51, 57 (E.D. Mich. 1982) ("There is also substantial ground for difference of opinion. This is a question of first impression regarding interpretation of an ambiguous statutory provision." (citation omitted) .

Although the Court recognized it must "apply the *Twombly* and *Iqbal* standards against the factors of *Actavis* in analyzing the Plaintiff's complaint,"[53] in so doing, it required level of detail that is not supported by *Twombly*, *Iqbal*, and Third Circuit precedent applying those cases. For example, the Third Circuit in *Phillips v. County of Allegheny*,[54] reiterated that, even post *Twombly* and *Iqbal*, "Rule 8 requires only a short and plan statement of the claim and its grounds."[55]

b. There are substantial grounds for a difference of opinion concerning whether a court should dismiss a complaint "with prejudice," where it has established a new pleading standard and not considered plaintiffs' evidence relating to that standard.

Even if the Court's imposition of a new, heightened pleading standard was appropriate, there is genuine doubt concerning the Court's decision to impose that standard upon Plaintiffs, without affording them the opportunity to meet it.

As argued in more detail in Plaintiffs' motion for reconsideration,[56] courts recognize the inherent unfairness in holding a litigant to a standard adopted after its pleading was submitted.[57] That is the case here, where this Court established a

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[53] Op. at 27.

[54] 515 F.3d 224 (3d Cir. 2008).

[55] *Phillips*, 515 F.3d at 232.

[56] *See* Direct Purchaser Class Plaintiffs' Memorandum of Law in Support of Their Motion for Reconsideration to Allow Repleading, October 21, 2014, which is adopted and incorporated herein.

[57] *See, e.g.*, *Advanced Micro Devices v. Samsung Elecs. Co.*, 2010 WL 963920, at *10-11 (N.D. Cal. Mar. 16, 2010) (allowing chance to re-plead in light of

new pleading standard when evaluating Plaintiffs' Complaint. As a result, Plaintiffs should have been given the ability to re-plead to meet this new standard.

Likewise, Plaintiffs have already demonstrated they are in possession of facts which, if considered, would meet the new standard.[58] Basic fairness, the language of Rule 15, and cases applying that rule all dictate that such allegations be considered.[59]

c. There are substantial grounds for a difference of opinion concerning the Court's conclusion that the no-AG payment to Teva was not "unexplained" within the meaning of *Actavis.*

Finally, the Court held that the payments to Teva were not "unexplained" because a "sufficient justification" for the payments was found in: (1) Defendants

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heightened pleading standard announced by the Federal Circuit for inequitable conduct claims after original pleading was filed); *O'Campo v. Ghoman*, 2011 WL 5510018, at *2 (E.D. Cal. Nov. 10, 2011) (noting that numerous courts have allowed plaintiffs a chance to re-plead following the ADA's announcement of a new pleading standard).

[58] Op. at 38, n.20 (discussing, but electing not to consider, Plaintiffs' submission of "a methodology used to calculate the no authorized generic agreement having a value of over $500 million.").

[59] *See, e.g., McMahon v. General Dynamics Corp.*, 933 F. Supp. 2d 682, 696–97 (D.N.J. 2013) (supplemental certification citing additional factual detail was not considered as part of the pleading, but the certification suggested that an amended complaint would not be futile; motion to amend therefore granted); *Blasband v. Rales*, 971 F.2d 1034, 1055 (3d Cir. 1992) (Third Circuit case law manifests "strong preference" that plaintiff be given leave to amend where amendment is likely to cure the defects in prior complaint; and plaintiff believes in good faith that he can satisfy the principles set forth by the Court).

submission of their agreements to the FTC before they became effective; (2) the FTC's reservation of the right to take further action at a later time; and (3) after getting this "lackluster response" from the FTC, Judge Martini entered a Consent Order approving the settlement.

These factors are irrelevant to whether a payment is "unexplained" or "justified" within the meaning of *Actavis*. To be sure, the *Actavis* Court said that there could be valid explanations for reverse payments, including the costs of anticipated litigation, payments for services to be rendered by the generic, and "any other convincing justification."[60] But, the Supreme Court's general concern in assessing antitrust conduct is to determine if there are "genuine adverse effects on competition."[61] Thus, the type of "justifications" that could legitimately "explain" a reverse payment are those which have genuine pro-competitive (or neutral) effects on competition.

The fact that Defendants submitted the agreement to the FTC for review is irrelevant to whether the agreement's provisions had genuine adverse "effects" on competition. (It is also irrelevant to whether the Defendants had "antitrust intent," as they were required by statute and a previous consent decree to submit the

[60] Op. at 42.

[61] Op. at 35, citing *Actavis*, 133 S.Ct. at 2234 (quoting *FTC v. Indiana Federation of Dentists*, 476 U.S. 447 (1986)).

agreement.[62]) Also irrelevant to whether the agreement had anticompetitive effects is the FTC's "lackluster response" to Judge Martini's Order.[63] All these facts show is that the FTC did not comprehensively review the agreement, and thus did not

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[62] Benign intentions are themselves irrelevant. *See, e.g., NCAA v. Board of Regents*, 468 U.S. 85, 101 n.23 (1984) ("Good motives will not validate an otherwise an anticompetitive practice.").

[63] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub, L. No. 108-173, § 1117, 117 Stat. 2066, 2461-63 (codified at 21 U.S.C. § 355) ("[A]ny failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provisions of law."). Courts in analogous contexts also recognize this. *Altria Group et al. v. Good*, 555 U.S. 70, 89-90 (2008) ("The FTC's failure to require petitioners to correct their allegedly misleading use of 'light' descriptors is not evidence [of FTC authorization]; agency non-enforcement of a federal statute is not the same as a policy of approval."); *Clomon v. Jackson*, 988 F.2d 1314, 1322 (2d Cir. 1993) (rejecting defendant's argument that he was not liable for a violation of the Fair Debt Collection Practices Act because the FTC was aware of his practice, and finding that "the fact that the FTC received copies of these letters and expressed no disapproval of them is not evidence that the FTC 'authoritatively interpreted' the letters as lawful or even that the FTC gave the letters its 'tacit approval'."); *Phonetele, Inc. v. American Tel. & Tel. Co.*, 664 F.2d 716, 727 n.32 (9th Cir. 1981) (agency's failure to review and approve or prohibit particular conduct that is within the scope of its authority is irrelevant to whether that practice is anticompetitive); *Meijer, Inc. v. Barr Pharms, Inc.*, 572 F. Supp. 2d 38, 53 n.18 (D.D.C. 2008) ("The Court rejects the idea that the FTC's investigation and ultimate filing of charges against Barr for a per se violation of the antitrust laws [where FTC initially failed to take action against Barr] somehow belies Barr's alleged anticompetitive conduct simply because the FTC did not move with the dispatch that Barr would expect."); *Static Control Components, Inc. v. Lexmark Int'l, Inc.*, 749 F. Supp. 2d 542, 556 (E.D. Ky. 2010) (restating the court's earlier finding that "Lexmark could not use the FTC's decision not to take action as a sword because inaction on the part of the government cannot be used to prove innocence, and therefore such inaction is irrelevant.").

find that the agreement's payments had pro-competitive explanations or justifications.[64]

By contrast, Plaintiffs alleged that there was a large net payment from Wyeth to Teva through the no AG provision, the purpose and effect of which was to delay generic entry for two years.[65] The adverse effects on competition from delayed generic entry are beyond dispute.[66] Once Plaintiffs show anticompetitive effects, it is Defendants' burden to show the existence of offsetting procompetitive effects or justifications.[67] Defendants here have not proffered any offsetting procompetitive justifications for these payments. Thus, these payments are

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[64] The FTC's general view on agreements of this type is clear. *See, e.g.*, Brief of FTC as *Amicus Curaie* [ECF # 264] at 16; *see also id*. at p. 16, n.17 ("The FTC has consistently categorized [no-authorized-generic commitments] as payments that can induce the generic company to end its patent challenge and stay out of the market." (citations omitted))

[65] Complaint at ¶ 2; PAC at ¶ 2.

[66] *See Actavis*, 133 S.Ct. at 2231 ("there is reason for concern that settlements taking this form tend to have significant adverse effects on competition").

[67] "If a plaintiff meets his initial burden of adducing adequate evidence of market power or actual anticompetitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective." *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1367-68 (3d Cir. 1996). Defendants' burden of proving the affirmative defense of pro-competitive justification is a heavy one. *NCAA v. Bd. Of Reg. of Univ. of Okla.*, 468 U.S. 85, 113 (1984) ("Under the Rule of Reason, these hallmarks of anticompetitive behavior place upon petitioner a heavy burden of establishing an affirmative defense which competitively justifies this apparent deviation from the operations of a free market.").

"unexplained" within the meaning of *Actavis*, and must be assessed under a full rule of reason analysis.[68]

3. **An immediate appeal will materially advance the outcome of the litigation.**

An interlocutory appeal materially advances termination of the litigation where it eliminates the need for a trial, complex issues, or any issues that make discovery more difficult and complex.[69] "Certification is more likely to materially advance the litigation where the appeal occurs early in the litigation, before extensive discovery has taken place and a trial date has been set."[70] That is the case here, where only limited discovery has taken place, and the litigation is in its infancy.[71]

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[68] This point is made in the article quoted by the Court in its Opinion, which analyzes the payment prong by valuing the consideration flowing to the alleged infringer (generic), deducting avoided litigation costs and consideration flowing to the patentee (brand), and concluding that "[t]he resulting net payment is 'otherwise unexplained.'" *See* Op. at 39 (quoting *Activating Actavis*, 16 Antitrust Vol. 28 at 18).

[69] *New Jersey Protection*, 2008 WL 4692345, at *3 (citation omitted); *see also Atmosphere Hosp. Mgmt. Servc., LLC v. Royal Realties, LLC*, 2014 WL 2938085 (E.D. Mich. June 26, 2014) ("An interlocutory appeal materially advances litigation when it 'save[s] judicial resources and litigant expenses.'" (citation omitted)).

[70] *Kaplan*, 2014 WL 4678059 at *3 (quoting *New Jersey Protection & Advocacy, Inc. v. New Jersey Dept. of Ed.*, 2008 WL 469345, at *3 (D.N.J. Oct. 8, 2008) (citation omitted)).

[71] *See, e.g. Kaplan*, 2014 WL 4678059 at *4 (litigation would be materially advanced by appeal, which would at most deprive the court of jurisdiction and at least clarify the proper avenues for discovery going forward); *In re Chocolate*

As discussed above under factor 5 of the 54(b) analysis, Count I (against Wyeth) and Count II (against both Wyeth and Teva) present different theories of liability, yet each caused a similar, related harm (supra-competitive prices because of delayed generic competition). Judicial economy and efficiency would be achieved by trying the two claims together. Doing so would avoid the danger of inconsistent jury verdicts, and the potential for duplicative damages being assessed against Wyeth. And, the parties and court could avoid the complicated issues that would arise at a second trial involving both Wyeth and Teva.

Full discovery in this case will take substantial time and effort. Much of the discovery that will take place while the *Walker Process* claim is being pursued will also relate to the RPSA claim. For example, discovery relating to market power, projected generic entry dates, forecasted impacts of generic entry and damages will overlap. Moving forward with discovery now, while simultaneously obtaining clarification from the Third Circuit on an expedited basis concerning the RPSA claim, is the most efficient manner of proceeding. If the Third Circuit reverses the Court's decision regarding the RPSA claim and allows that claim to proceed, the parties will simply have to perform targeted discovery concerning the negotiation

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Confectionary, 607 F. Supp.2d at 707-08 (certification would materially advance the termination of the litigation where complex, costly discovery had not yet commenced).

of the agreement, and its anticompetitive and any cognizable procompetitive effects, before readying for trial.[72] If the Third Circuit upholds the Court's Opinion on the RPSA claim, the parties will not have lost any time in moving the *Walker Process* claim towards a resolution.

Certification of these issues, and an expedited appellate resolution as to Count II, would materially advance the termination of this litigation by ensuring that the Count I efficiently progresses towards a single trial.

V. CONCLUSION

For the aforementioned reasons, Plaintiffs respectfully request that the Court grant Plaintiffs' motion for entry of judgment pursuant to Fed. R. Civ. P. 54(b) or, in the alternative, grant Plaintiffs' motion for certification of an interlocutory appeal pursuant to 28 U.S.C. 1292(b).

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Respectfully submitted,

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[72] *See, e.g., Dalie v. Pulte Home Corp.*, 636 F.Supp.2d 1025, 1030 (E.D. Cal. 2009) (it would materially advance the termination of the litigation to permit interlocutory appeal in an attempt to avoid the possibility of two significantly duplicative trials).

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